

FORM PTO-1390 (Modified) U.S. PATENT AND TRADEMARK OFFICE; U.S. DEPARTMENT OF COMMERCE
(REV. 12-2004)

**TRANSMITTAL LETTER TO THE UNITED STATES
DESIGNATED/ELECTED OFFICE (DO/EO/US)
CONCERNING A SUBMISSION UNDER 35 U.S.C. 371**

ATTORNEY'S DOCKET NUMBER

17766 (PC27648A)

U.S. APPLICATION NO. (If known, see 37 CFR 1.5)

10/522253INTERNATIONAL APPLICATION NO.
PCT/EP2003/007851INTERNATIONAL FILING DATE
16 July 2003 (16-07-2003)PRIORITY DATE CLAIMED
25 July 2002 (25-07-2002)

TITLE OF INVENTION

**BICYCLO-PYRAZOLES ACTIVE AS KINASE INHIBITORS, PROCESS FOR THEIR PREPARATION AND
PHARMACEUTICAL COMPOSITIONS COMPRISING THEM**

APPLICANT(S) FOR DO/EO/US

**Manuela Villa Daniele Fancelli Anna Vulpetti
Francesca Abrate Mario Varasi**

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☒ This is a **FIRST** submission of items concerning a submission under 35 U.S.C. 371.
2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a submission under 35 U.S.C. 371.
3. ☐ This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (24) indicated below.
4. ☒ The US has been elected (Article 31).
5. ☒ A copy of the International Application as filed (35 U.S.C. 371 (c)(2))
 - a. ☐ is attached hereto (required only if not communicated by the International Bureau).
 - b. ☒ has been communicated by the International Bureau.
 - c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☐ An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).
 - a. ☐ is attached hereto.
 - b. ☐ has been previously submitted under 35 U.S.C. 154(d)(4).
7. ☒ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371 (c)(3))
 - a. ☐ are attached hereto (required only if not communicated by the International Bureau).
 - b. ☐ have been communicated by the International Bureau.
 - c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
 - d. ☒ have not been made and will not be made.
8. ☐ An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9. ☐ An oath or declaration of the inventor(s) (35 U.S.C. 371 (c)(4)).
10. ☐ An English language translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371 (c)(5)).
11. ☐ A copy of the International Preliminary Examination Report (PCT/IPEA/409).
12. ☒ A copy of the International Search Report (PCT/ISA/210).

Items 13 to 23 below concern document(s) or information included:

13. ☐ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
14. ☐ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
15. ☒ A **FIRST** preliminary amendment.
16. ☐ A **SECOND** or **SUBSEQUENT** preliminary amendment.
17. ☐ A substitute specification.
18. ☐ A power of attorney and/or change of address letter.
19. ☐ A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821 - 1.825.
20. ☐ A second copy of the published International Application under 35 U.S.C. 154(d)(4).
21. ☐ A second copy of the English language translation of the International Application under 35 U.S.C. 154(d)(4).
22. ☐ Express Mail Label No. **EV213895935US**
23. ☒ Other items or information:

**Assignee: Pharmacia Italia S.p.A. of Milan, Italy
Courtesy Copy of International Application**

DT01 Rec'd PCT/PTC 25 JAN 2005

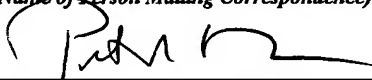
PTO-1390 (Rev. 12-2004)

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

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|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------|-------------------------------------------------------------------------------|------------|--------------------------|-----------------|
| U.S. APPLICATION NO. (If known, see 37 CFR 1.5) | | INTERNATIONAL APPLICATION NO. | | ATTORNEY'S DOCKET NUMBER | |
| 10/522253 | | PCT/EP2003/007851 | | 17766 (PC27648A) | |
| 24. The following fees are submitted: | | | | Applicant use | Office use only |
| <input checked="" type="checkbox"/> a) Basic national fee | | | | \$300.00 | |
| <input checked="" type="checkbox"/> b) Examination fee | | | | \$200.00 | |
| <input checked="" type="checkbox"/> c) Search fee | | | | \$500.00 | |
| TOTAL OF ABOVE CALCULATIONS = | | | | \$1,000.00 | |
| <input type="checkbox"/> Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing or computer program listing filed in an electronic medium). The fee is \$250 for each additional 50 sheets of paper or fraction thereof. | | | | | |
| Total Sheets | Extra Sheets | Number of each additional 50 or fraction thereof (round up to a whole number) | RATE | | |
| 80 - 100 = | -20 /50 = | 0 | x \$250.00 | \$0.00 | |
| Surcharge of \$130.00 for furnishing the oath or declaration later than months from the earliest claimed priority date (37 CFR 1.492(e)). | | | | \$130.00 | |
| CLAIMS | NUMBER FILED | NUMBER EXTRA | RATE | | |
| Total claims | * 32 - 20 = | 12 | x \$50.00 | \$600.00 | |
| Independent claims | * 2 - 3 = | 0 | x \$200.00 | \$0.00 | |
| MULTIPLE DEPENDENT CLAIMS (if applicable) <input checked="" type="checkbox"/> + | | | | \$360.00 | |
| TOTAL OF ABOVE CALCULATIONS = | | | | \$2,090.00 | |
| <input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. The fees indicated above are reduced by 1/2. | | | | \$0.00 | |
| SUBTOTAL = | | | | \$2,090.00 | |
| Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(f)). | | | | \$0.00 | |
| TOTAL NATIONAL FEE = | | | | \$2,090.00 | |
| Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40 per property | | | | \$200.00 | |
| TOTAL FEES ENCLOSED = | | | | \$2,090.00 | |
| *Claim calculation based on claims as amended by Preliminary Amendment being filed concurrently herewith | | | | Amount to be refunded: | \$ |
| | | | | Amount to be charged: | \$ |
| a. <input checked="" type="checkbox"/> A check in the amount of \$ <u>\$2,090.00</u> to cover the above fees is enclosed. | | | | | |
| b. <input type="checkbox"/> Please charge my Deposit Account No. _____ in the amount of _____ to cover the above fees. A duplicate copy of this sheet is enclosed. | | | | | |
| c. <input checked="" type="checkbox"/> The Director is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. <u>19-1013/SSMP</u> . A duplicate copy of this sheet is enclosed. | | | | | |
| d. <input type="checkbox"/> Fees are to be charged to a credit card. WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038. | | | | | |
| NOTE: Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the International Application to pending status. | | | | | |
| SEND ALL CORRESPONDENCE TO: | | | | | |
| Scully, Scott, Murphy & Presser | | | | | |
| 400 Garden City Plaza-Suite 300 | | | | | |
| Garden City, New York 11530 | | | | | |
| 516-742-4343 | | | | | |
| | | | | SIGNATURE | |
| | | | | Peter I. Bernstein | |
| | | | | NAME | |
| | | | | 43,497 | |
| | | | | REGISTRATION NUMBER | |

| | |
|---------------------|------|
| FEE VALUE | |
| ACCOUNTABILITY | |
| DEPOSIT ACCOUNT NO. | |
| 19 | 1013 |
| 163 500 | |
| 1642 400 | |
| 165 1600 | |
| 1615 500 | |

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|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|------------------------|--------------------------------|-------------------------------|
| CERTIFICATE OF MAILING BY "EXPRESS MAIL" (37 CFR 1.10) | | | 104522253 Docket No. | |
| Applicant(s): Manuela Villa, et al. | | | 17766 (PC27648A) | |
| Application No. Unassigned | Filing Date Herewith | Examiner Unassigned | Customer No. 23389 | 25 JAN 2005 Group Art Unit |
| Invention: BICYCLO-PYRAZOLES ACTIVE AS KINASE INHIBITORS, PROCESS FOR THEIR PREPARATION AND PHARMACEUTICAL COMPOSITIONS COMPRISING THEM | | | | |
| I hereby certify that the following correspondence: <div style="border: 1px solid black; padding: 5px; margin: 10px 0;">New U.S. Application Under 35 U.S.C. 371</div> <p style="text-align: center;"><i>(Identify type of correspondence)</i></p> <p>is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on <u>January 25, 2005</u> <i>(Date)</i></p> <div style="text-align: right; margin-top: 20px;"><div style="margin-bottom: 10px;">Peter I. Bernstein <i>(Typed or Printed Name of Person Mailing Correspondence)</i></div><div style="margin-bottom: 10px;"> <i>(Signature of Person Mailing Correspondence)</i></div><div>EV213895935US <i>("Express Mail" Mailing Label Number)</i></div></div> | | | | |
| Note: Each paper must have its own certificate of mailing. | | | | |